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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,663	08/31/2005	Shizuo Akira	31671-211618	1905
26694	7590	11/20/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			BERTOGGIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/517,663

Applicant(s)

AKIRA, SHIZUO

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-16 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/13/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply dated 09/07/2006 has been received. Claims 1-7 and 17-19 have been cancelled. Claims 8-16 are withdrawn. Claims 20-24 have been added.

Newly submitted claims 21-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 21-24 belong to Groups II and III, which lack unity as set forth at pages 4-5 of the restriction requirement dated 04/04/06. The groups lack a special technical feature that is a contribution over the prior art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

However, upon allowance of the product claims, each of the presented process claims will be rejoined as follows. **It is noted, that for the process claims to be allowable along with the product, active method steps in the claims are required** (see MPEP 2173.05(q)).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 8-16 and 20-24 are pending. Claims 8-16 and 21-24 are withdrawn. Claim 20 is under consideration in the instant office action.

Priority

Acknowledgment is made of an English translation of Japanese patent application No. 2002-173254, filed June 13, 2002.

Information Disclosure Statement

The submission of an English translation of reference A6 from the IDS dated 12/13/2004 is acknowledged. This Abstract has been considered and an initialed copy of the PTO-1449 is included with the instant office action.

Double Patenting

The rejection of claims 1, 5 and 6 as being provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 52 of copending Application No. 09/889,324 in view of Thoma-Uszynski et al (Science, 291:1544-1547; 2001) is withdrawn. Claims 1, 5, and 6 have been cancelled and the newly added claims are clearly limited to disruption of the TLR1 gene, which is not obvious over '324.

Claim Objections

The objection to claim 4 is withdrawn.

Claim 20 is objected to because of the following informalities:

Claim 20 is objected to because the phraseology is awkward with independent sentences within the claim. More appropriate claim structure would include: A transgenic mouse whose genome comprises a homozygous inactivation of the Toll-like Receptor 1 (TLR1) gene, said TLR-1 gene encoding a polypeptide that recognizes triacylated mycobacterial lipoproteins, wherein peritoneal macrophages of the mouse, also comprising a homozygous inactivation of the TLR-1 gene, exhibit decreased responsiveness to triacylated mycobacterial lipoproteins. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

The rejection of claims 1-7 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full breadth of the claim is withdrawn as it relates to newly added claim 20. Claim 20 recites the necessary limitations to overcome the rejection of record.

Written Description

The rejection of claims 1-3, 5 and 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn as it relates to the newly added claim. Claim 20 recites the necessary limitations to overcome the rejection of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

However a new grounds of rejection is set forth below.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is unclear because line 5 recites that the macrophages also comprises a homozygous disruption of TLR1. However, the genome of the mouse is recited to comprise an inactivation of TLR1. A disruption is greater in breadth than an inactivation and does not necessarily indicate an inactivation. Therefore, to the extent that the claim reads that the macrophages “also” comprise a disruption but the mouse is not recited to have a “disruption”, the claim is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) The rejection of claims 1-7 under 35 U.S.C. 102(a) as being anticipated by Takeuchi et al (The Journal of Immunology, 169:10-14, July 2002) is withdrawn in light of the certified English translation of the foreign priority document, Japanese patent application No. 2002-173254, filed June 13, 2002.

2) The rejection of claims 1-7 under 35 U.S.C. 102(a) as being anticipated by Alexopoulou et al (Nature Medicine, 8:878-884, August 2002) as evidenced by Takeuchi et al (The Journal of Immunology, 169:10-14, 2002) is withdrawn in light of the certified English translation of the foreign priority document, Japanese patent application No. 2002-173254, filed June 13, 2002.

3) The rejection of claims 1-7 under 35 U.S.C. 102(a) as being anticipated by Henneke et al (Journal of Immunology, 167:7069-7076, 12/15/2001) is maintained as it applies to newly added claim 20.

Henneke teaches a TLR1 knockout mouse (page 7070, col. 2, paragr. 3, lines 1-3; page 7072, col. 2, paragraph 2, lines 5-6). Thus, Henneke anticipates the instant claims.

It is noted that:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best*, 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

Applicant's arguments filed 09/07/2006 have been fully considered but they are not persuasive. Applicant argues that Henneke *et al.* only describe that macrophages of TLR1 knockout mice respond normally to a factor extracted from group B streptococcus, which is not a lipoprotein (page 7, last paragraph, of Applicant's Remarks). Hence, it appears Applicant is arguing that Henneke *et al.* does not teach the claimed phenotype of decreased responsiveness to triacylated mycobacterial lipoproteins. This

argument is not persuasive because the absence of a teaching regarding an inherent property of the TLR-1 knockout mouse does not constitute evidence that the inherent property was not present.

Applicant also argues that Henneke *et al.* does not disclose a method for using TLR1 knockout mice as a model non-responsive to triacylated mycobacterial lipoprotein. This argument is not relevant to claim 20 and the method claims are not currently under consideration, as the product claim is not allowable.

Therefore, because Henneke *et al.* teach a mouse whose genome comprises an inactivation of the TLR1 gene (TLR1^{-/-}), it is maintained that the mouse of Henneke *et al.* inherently would exhibit the claimed characteristics that result from the inactivation.

4) The rejection of claims 1, 2, 5 and 6 under 35 U.S.C. 102(b) as being anticipated by Thoma-Uszynski *et al* (Science, 291:1544-1547, 2001) as evidenced by Takeuchi *et al* (International Immunology, 13:933-940, 2001) is withdrawn in light of Applicant's of Applicant's cancellation of the claims and limitations of the new claims to TLR1. Thoma-Uszynski *et al.* did not teach inactivation of the TLR1 gene.

Conclusions

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment and provide any statements that might help to identify support for the claimed invention (e.g. if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Valarie Bertoglio
Examiner
Art Unit 1632